The following corrections or additions to the January 15, 1998 list were made in November, 1998

New Approvals

ANADA Number: 200-225

Pioneer Product:	112-051
Trade Name:	Prohibit™ Soluble Drench Powder
Ingredients:	Levamisole hydrochloride
Sponsor:	Agri Laboratories, Ltd.
Approval Date:	08/27/98
Status:	Over-the-counter
Route:	Oral
Species:	Bovine, ovine
Drug Form:	Powder
Concentration:	46.8 g levamisole hydrochloride activity in 52 g of powder (packet) or 544.5 g levamisole hydrochloride activity in 605 g of powder (bottle).
Indications:	As an anthelmintic effective against stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*), lung worms (*Dictyocaulus*) in cattle and sheep; and *Chabertia* in sheep only.
Tolerance:	21CFR 556.350: A tolerance of 0.1 ppm is established for levamisole residues in the uncooked edible tissues of cattle and sheep.
Withdrawal:	Cattle: 2 days Sheep: 3 days

21CFR 520.1242a

ANADA Number: 200-238

Pioneer Product:	046-285
Trade Name:	Sulfasol® Soluble Powder
Ingredients:	Sulfadimethoxine
Sponsor:	Med-Pharmex, Inc.
Approval Date:	07/28/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (chickens, turkeys), bovine (dairy calves, dairy heifers, beef cattle)
Drug Form:	Powder
Concentration:	94.6 g sulfadimethoxine (base)/107 g packet
Indications:	Chickens (broilers and replacements only): For the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. Turkeys (meat producing only): For the treatment of disease outbreaks of coccidiosis and fowl cholera. Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella spp.* sensitive to sulfadimethoxine and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.
Tolerance:	21CFR 556.640: Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues at 0.1 ppm, and milk at 0.01 ppm (negligible residue).
Withdrawal:	Chickens (broilers and replacements only): 5 days Turkeys (meat producing only): 5 days Dairy calves, dairy heifers, and beef cattle: 7 days

21CFR 520.2220a

ANADA Number: 200-251

Pioneer Product:	031-205
Trade Name:	Sulforal®
Ingredients:	Sulfadimethoxine
Sponsor:	Med-Pharmex, Inc.
Approval Date:	08/03/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (chickens, turkeys), bovine (dairy calves, dairy heifers, beef cattle)
Drug Form:	Liquid (solution)
Concentration:	12.5 %
Indications:	Chickens (broilers and replacements): For the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza. Turkeys (meat producing): For the treatment of disease outbreaks of coccidiosis and fowl cholera. Dairy calves, dairy heifers, and beef cattle: For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella spp.* sensitive to sulfadimethoxine and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.
Tolerance:	21CFR 556.640: Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues at 0.1 ppm (negligible residue) and in milk at 0.01 ppm (negligible residue).
Withdrawal:	Chickens (broilers and replacements): 5 days Turkeys (meat producing): 5 days Dairy calves, dairy heifers, and beef cattle: 7 days

21CFR 520.2220a

ANADA Number: 200-259

Pioneer Product:	200-091
Trade Name:	ChlorMax™, Sacox®, 3-Nitro®
Ingredients:	Chlortetracycline, salinomycin sodium, roxarsone
Sponsor:	Alpharma, Inc.
Approval Date:	09/21/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (broiler chickens)
Drug Form:	Type A medicated article to make Type C medicated feed
Concentration:	Chlortetracycline – 50, 65, and 70 g/lb in Type A Medicated Articles Salinomycin – 30 and 60 g/lb in Type A Medicated Articles Roxarsone – 10, 20 and 50% (45.4, 90.8, 227 g/lb) in Type A Medicated Articles
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments.
Tolerance:	21CFR 556.150 Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat. 21CFR 556.60 Roxarsone: Tolerances of arsenic (from roxarsone) are established at 0.5 ppm in uncooked muscle tissue and 2 ppm in uncooked edible by-products with liver as the target tissue. Salinomycin does not require a tolerance.
Withdrawal:	5 days

This ANADA provides for the combined use of three approved Type A Medicated Articles in Type C medicated feeds, rather than a premix incorporating all three of these.

21CFR 558.550

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: 200-260

Pioneer Product:	140-867
Trade Name:	ChlorMax™, Bio-Cox®, 3-Nitro®
Ingredients:	Chlortetracycline, salinomycin sodium, roxarsone
Sponsor:	Alpharma, Inc.
Approval Date:	09/21/98
Status:	Over-the-counter
Route:	Oral
Species:	Avian (broiler chickens)
Drug Form:	Type A medicated article to make Type C medicated feed
Concentration:	Chlortetracycline – 50, 65, and 70 g/lb in Type A Medicated Articles Salinomycin – 30 and 60 g/lb in Type A Medicated Articles Roxarsone – 10, 20 and 50% (45.4, 90.8, 227 g/lb) in Type A Medicated Articles
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments.
Tolerance:	21CFR 556.150 Chlortetracycline: Tolerances for the sum of residues of the tetracycline, including chlortetracycline in tissues of chickens are: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat. 21CFR 556.60 Roxarsone: Tolerances of arsenic (from roxarsone) are established at 0.5 ppm in uncooked muscle tissue and 2 ppm in uncooked edible by-products with liver as the target tissue. Salinomycin does not require a tolerance.
Withdrawal:	5 days

This ANADA provides for the combined use of three approved Type A Medicated Articles in Type C medicated feeds, rather than a premix incorporating all three of these.

21CFR 558.550

Supplemental Approvals

NADA Number: 122-578

Trade Name:	Hyvisc® Sterile Injection
Ingredients:	Hyaluronate sodium
Sponsor:	Anika Therapeutics, Inc.
Approval Date:	09/30/98
Status:	Prescription only
Route:	Intra-articular
Species:	Equine
Drug Form:	Liquid (solution)
Concentration:	11 mg/mL
Indications:	For the treatment of joint dysfunction due to non-infectious synovitis associated with equine osteoarthritis.

This supplemental application provides for the increase in concentration of hyaluronate sodium from 10 mg/mL to 11 mg/mL and increase the dose from 20 mg to 22 mg for small joints and from 40 mg to 44 mg for large joints.

21CFR 522.1145 and 510.600

NADA Number: 041-061

Trade Name:	Mecadox® 10 Type A Medicated Article
Ingredients:	Carbadox
Sponsor:	Pfizer, Inc.
Approval Date:	10/05/98
Status:	Over-the-counter
Route:	Oral
Species:	Porcine
Drug Form:	Type A medicated article to make Type B and Type C medicated feeds.
Concentration:	10 g/lb
Indications:	For control of swine dysentery (vibrionic dysentery, bloody scours, or hemorrhagic dysentery); bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis);* and for increased weight gain and improved feed efficiency in growing swine.
Tolerance:	21CFR 556.100: A tolerance of 30 ppb is established for residues of quinoxaline-2-carboxylic acid (marker residue) in liver (target tissue) of swine.
Withdrawal:	42 days

This supplemental application provides for the establishment of a 42 day slaughter withdrawal period for carbadox in swine tissues and a limitation against use in pregnant swine or swine intended for breeding purposes.

21CFR 558.115

NADA Number: 141-079

Trade Name:	Ivomec® Eprinex™ Pour-On for Beef and Dairy Cattle
Ingredients:	Eprinomectin
Sponsor:	Merial Ltd.
Approval Date:	08/09/98
Status:	Over-the-counter
Route:	Topical
Species:	Bovine
Drug Form:	Liquid (solution)
Concentration:	5 mg/mL
Indications:	For the treatment and control of the following parasites: Gastrointestinal Roundworms - *Haemonchus placei* (adults and L4), *Ostertagia ostertagi* (adults and L4, including inhibited L4), *Trichostrongylus axei* (adults and L4), *Trichostrongylus colubriformis* (adults and L4), *Trichostrongylus longispicularis* (adults only), *Cooperia oncophora* (adults and L4), *Cooperia punctata* (adults and L4), *Cooperia surnabada* (adults and L4), *Nematodirus helvetianus* (adults and L4), *Oesophagostomum radiatum* (adults and L4), *Bunostomum phlebotomum* (adults and L4), *Strongyloides papillosus* (adults only), *Trichuris spp* (adults only) Lung worms - *Dictyocaulus viviparus* (adults and L4) Cattle Grubs (all parasitic stages) – *Hypoderma lineatum, Hypoderma bovis* Lice – *Damalinia bovis, Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus* Mange Mites – *Chorioptes bovis, Sarcoptes scabiei* Horn Flies – *Haematobia irritans*
Tolerance:	21CFR 556.227: The Acceptable Daily Intake (ADI) for total residues of eprinomectin is 10 mcg/kg body weight/day. A tolerance of 100 ppb is established for residues of eprinomectin B_1a (marker residue) in muscle, 12 ppb in milk, and 4.8 ppm in liver (target tissue).
Withdrawal:	Zero days
Patent Number:	4,427,663 Expiration Date: 03/16/2002 5,602,107 05/10/2013
Exclusivity:	3 years

This supplemental application provides for adding to the indications for the treatment and control of adult *Strongyloides papillosus* and adult *Trichostrongylus longispicularis* and removes the age restriction for use in cattle under 8 weeks of age.

21CFR 524.814 and 556.227

NADA Number: 141-043

Trade Name:	Synovex® Plus™
Ingredients:	Trenbolone acetate, estradiol benzoate
Sponsor:	Fort Dodge Animal Health, Division of American Home Products Corp.
Approval Date:	09/30/98
Status:	Over-the-counter
Route:	Subcutaneous (implantation, ear)
Species:	Bovine (heifers and steers)
Drug Form:	Implant
Concentration:	200 mg trenbolone acetate and 28 mg estradiol benzoate/implant
Indications:	For increased rate of weight gain in heifers fed in confinement for slaughter.
Tolerance:	21CFR 556.739 Trenbolone: A tolerance for tenbolone residues in uncooked edible tissues of cattle is not needed. The safe concentrations for total trenbolone residues in uncooked edible tissues of cattle is 50 ppb for muscle, 100 ppb for liver, 150 ppb for kidney, and 200 ppb for fat. 21CFR 556.240 Estradiol: Residues of estradiol and related esters may not exceed the following increments above the concentrations of estradiol naturally present in untreated animals; in uncooked edible tissues of heifers, steers, and calves, 120 ppt for muscle, 480 ppt in fat, 360 ppt for kidney, and 240 ppt for liver.
Withdrawal:	Not required.
Exclusivity:	3 years

This supplemental application provides for the implantation of Synovex® Plus™ in a new class of cattle (heifers) fed in confinement for slaughter for increased rate of weight gain.

21CFR 522.2478

NADA Number: 048-761

Trade Name:	Aureomycin Type A Medicated Article
Ingredients:	Chlortetracycline
Sponsor:	Roche Vitamins, Inc.
Approval Date:	10/26/98
Status:	Over-the-counter
Withdrawal:	Zero days

This supplemental application provides for reducing the withdrawal period from 24 hours to zero days when administered at the 500 g/ton level for 5 days for reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.

21CFR 559.128

Actions Taken by FDA Center for Veterinary Medicine

Technical Amendment

NADA Number: 128-620

Trade Name:	Safe-Guard® and Panacur® Suspension 10%
Ingredients:	Fenbendazole
Sponsor:	Hoechst Roussel Vet
Effective Date:	11/18/98
Status:	Over-the-counter and prescription only
Route:	Oral
Species:	Bovine
Drug Form:	Liquid (suspension)
Concentration:	100 mg/mL
Indications:	For the removal and control of: Cattle: Lung worm - *Dictyocaulus viviparus* Stomach worms - *Ostertagia ostertagi* (adults) - *Haemonchus contortus/placei* (adult and L4), *Trichostrongylus axei* Intestinal worms (adult and L4) - *Bunostomum phlebotomum, Nematodirus helvetianus, Cooperia oncophora, Cooperia punctata, Trichostrongylus colubriformis, Oesophagostomum radiatum* Beef cattle only: Stomach worm - *Ostertagia ostertagi* type II Ostertagiasis (4^{th} stage inhibited larvae) Tapeworm - *Moniezia benedi*
Tolerance:	21CFR 556.275: A tolerance of 0.8 ppm parent fenbendazole (the marker residue) in cattle liver (the target tissue) was established with the original approval. The safe concentrations for total residues of fenbendazole in edible tissues of cattle are 5 ppm in muscle, 10 ppm in liver, 15 ppm in kidney, and 20 ppm in fat. A safe concentration for total residues of fenbendazole of 1.67 ppm and 0.6 ppm tolerance was established.
Withdrawal:	8 days; zero days for milk.

This technical amendment and supplemental application clarifies the drug dose used to treat various classes of cattle, and provides for the removal and control of gastrointestinal parasites and lung worm in a new class of cattle, dairy cattle of breeding age.

21CFR 520.905a

Change of Sponsor Name

NADA Number: 122-578

From: Anika Research, Inc.
To: Anika Therapeutics, Inc.
236 West Cummings Park
Woburn, MA 01801
Drug labeler code: 060865

Change of Sponsor

NADA Number: 200-073

From: American Veterinary Products, Inc.
To: Veterinary Research Associates, Inc.
20 Old Dock Rd.
Yaphank, NY 11980
Drug labeler code: 064408